



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donald L. Wise, Debra J. Trantolo, David D. Hile and Stephen A. Doherty

Serial No.: 10/613,975

Art Unit: 1642

Filed: July 3, 2003

Examiner: Khatol S. Shahnan Shah

For: *VACCINES TO INDUCE MUCOSAL IMMUNITY*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESUBMISSION OF INFORMATION DISCLOSURE STATEMENT

Sir:

An Information Disclosure Statement, including eight (8) pages of Form PTO-1449 was filed in the U.S. Patent and Trademark Office on October 28, 2003. The Examiner has indicated that this Information Disclosure Statement has not yet been received by the U.S. Patent and Trademark Office. Accordingly, Applicants enclose copies of the Information Disclosure Statement, including eight (8) pages of Form PTO-1449, sixty-eight documents cited therein, and the Certificate of Mailing filed on October 28, 2003.

It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

Respectfully submitted,



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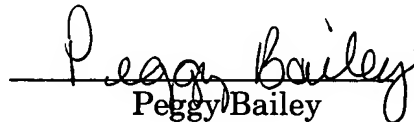
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Peggy Bailey

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Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including eight (8) pages of Form PTO-1449 and copies of the sixty-eight documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
5,429,822	07-04-1995	Gresser, et al.	424/426
5,456,917	10-10-1995	Wise, et al.	424/426

Publications

ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," *Pharm. Res.* 10(7): 945-953 (1993).

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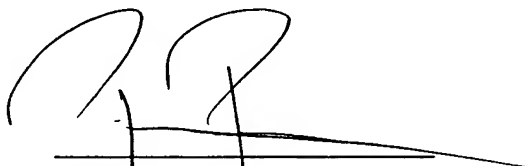
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Dated: October 28, 2003

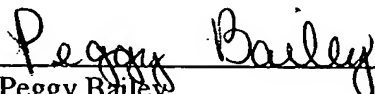
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One Atlantic Center
1201 West Peachtree Street, N.E.
Suite 2000
Atlanta, Georgia 30309-3400
404-817-8473
FAX 404-817-8588
www.hklaw.com

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Peggy Bailey

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			10/613,975	
			Filing Date	
			July 3, 2003	
			First Named Inventor	
			Donald L. Wise	
			Group Art Unit	
			1642	
			Examiner Name	
			Attorney Docket Number	
			CSI 130	

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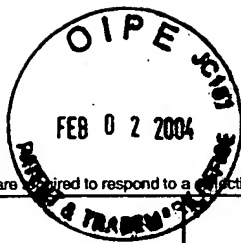
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Sheet 2 of 8

OTHER ART -- NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," <i>Pharm. Res.</i> 10(7): 945-953 (1993).	
		ANCHORDOQUY & KOE, "Physical stability of nonviral plasmid-based therapeutics," <i>J. Pharm. Science.</i> 89(3): 289-296 (2000).	
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		DOOLAN, et al., "Circumventing genetic restriction of protection against malaria with multigene DNA immunization: CD8 ⁺ T cell-, Interferon γ -, and nitric oxide-dependent immunity," <i>J. Exp. Med.</i> 183: 1739-1746 (1996).	
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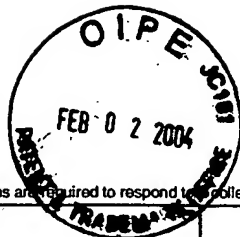
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		GORDON, et al., "Proteolytic activation of bacterial toxins by eukaryotic cells is performed by furin and by additional cellular proteases," <i>Infect. Immun</i> 63: 82-87 (1995).	
		GU, et al., "Protection against anthrax toxin by vaccination with a DNA plasmid encoding anthrax protective antigen," <i>Vaccine</i> 17: 340-344 (1999).	
		GUPTA, et al., "Involvement of residues 147VYYEIGK153 in binding of lethal factor to protective antigen of <i>Bacillus anthracis</i> ," <i>Biochem. Biophys. Res. Commun.</i> 280: 158-163 (2001).	
		GUY, et al., "Effects of the nature of adjuvant and site of parenteral immunization on the serum and mucosal immune responses induced by a nasal boost with a vaccine alone," <i>Clin. Diagn. Lab. Immunol.</i> 5(5): 732-736 (1998).	
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		HOFFMAN, et al., "Toward clinical trials of DNA vaccines against malaria," <i>Immun. Cell Biol.</i> 75: 376-381 (1997).	
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		IVINS, et al., "Recent advances in the development of an improved human anthrax vaccine," <i>Eur. J. Epidemiol.</i> 4: 12-19 (1988).	
		KAWABATA, et al., "The fate of plasmid DNA after intravenous injection in mice: involvement of scavenger receptors in its hepatic uptake," <i>Pharm. Res.</i> 12(6): 825-830 (1995).	

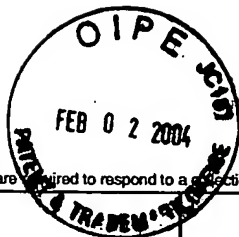
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/613,975
Filing Date	July 3, 2003
First Named Inventor	Donald L. Wise
Group Art Unit	1642
Examiner Name	
Attorney Docket Number	CSI 130

Sheet	5	of	8
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		KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci., USA</i> 89: 10277-10281 (1992).	
		KLINMAN, et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection," <i>Infect. Immunol.</i> 67: 5658-5663 (1999).	
		KRIEG, et al., "CpG DNA induces sustained IL-12 expression in vivo and resistance to <i>Listeria monocytogenes</i> challenge," <i>J. Immunol.</i> 161: 2428-2434 (1998).	
		KUPER, et al., "The role of nasopharyngeal lymphoid tissue," <i>Immunol. Today</i> 13(6): 219-224 (1992).	
		LABHASETWAR, et al., "A DNA controlled-release coating for gene transfer: transfection in skeletal and cardiac muscle," <i>J. Pharm. Science</i> 87(11): 1347-1350 (1998).	
		LE, et al., "Safety, tolerability and humoral immune responses after intramuscular administration of a malaria DNA vaccine to healthy adult volunteers," <i>Vaccine</i> 18: 1893-1901 (2000).	
		LEE, et al., "Immunization of rhesus monkeys with a mucosal prime, parenteral boost strategy protects against infection with <i>Helicobacter pylori</i> ," <i>Vaccine</i> 17: 3072-3082 (1999).	
		LEPPLA, et al., "Proteolytic activation of anthrax toxin bound to cellular receptors," in <i>Bacterial protein toxins</i> (Fehrenbach, et al., eds) pp. 111-112, Gustav Fischer: New York (1988).	
		LEPPLA, "Anthrax toxin edema factor: a bacterial adenylate cyclase that increases cyclic AMP concentrations in eukaryotic cells," <i>Proc. Natl. Acad. Sci. USA</i> 79: 3162-3166 (1982).	
		LITTLE & KNUDSON, "Comparative efficacy of <i>Bacillus anthracis</i> live spore vaccine and protective antigen vaccine against anthrax in the guinea pig," <i>Infect. Immun.</i> 52(2): 509-512 (1986).	

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		Filing Date	July 3, 2003
		First Named Inventor	Donald L. Wise
		Group Art Unit	1642
		Examiner Name	
Sheet 6 of 8	Attorney Docket Number	CSI 130	

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		LUNSFORD, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," <i>J. Drug. Target.</i> 8(1): 39-50 (2000).	
		LUO, et al., "Synthetic DNA delivery systems," <i>Nature Biotech</i> 18: 33-37 (2000).	
		MCGHEE, et al., "The mucosal immune system: from fundamental concepts to vaccine development," <i>Vaccine</i> 10(2): 75-88 (1992).	
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		NEUTRA, et al., "Antigen sampling across epithelial barriers and induction of mucosal immune responses," <i>Ann. Rev. Immunol.</i> 14: 275-300 (1996).	
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		O'HAGAN, et al., "Long-term antibody response in mice following subcutaneous immunization with ovalbumin entrapped in biodegradable microparticles," <i>Vaccine</i> 11(9): 965-969 (1993).	
		PARTIDOS, et al., "Mucosal immunization with a measles virus CTL epitope encapsulated in biodegradable PLG microparticles," <i>J. Imm. Meth.</i> 195: 135-138 (1996).	
		PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," <i>J. Control. Rel.</i> 75: 211-224 (2001).	

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		Filing Date	July 3, 2003
		First Named Inventor	Donald L. Wise
		Group Art Unit	1642
		Examiner Name	
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		PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," <i>Vaccine</i> 13(15): 1427-1430 (1995).	
		PRICE, et al., "Protection against anthrax lethal toxin challenged by genetic immunization with a plasmid encoding the lethal factor protein," <i>Infect. Immunity</i> . 69(7): 4509-4515 (2001).	
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		SMITH, et al., "Induction of secretory immunity with bioadhesive poly (D,L-lactid-co-glycolide) microparticles containing <i>Streptococcus sobrinus</i> glucosyltransferase," <i>Oral. Microbiol. Immunol.</i> 15: 124-130 (2000).	
		STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against <i>Plasmodium falciparum</i> malaria," <i>N. Engl. J. Med.</i> 336: 86-91 (1997).	
		THOMASIN, et al., "Tetanus toxoid and synthetic malaria antigen containing poly(lactide)/poly(lactide-co-glycolide) microspheres: importance of polymer degradation and antigen release for immune response," <i>J. Control. Rel.</i> 41: 131-145 (1996).	
		TINSLEY-BROWN, et al., "Formulation of poly (D,L-lactide-co-glycolic acid) microparticles for rapid plasmid DNA delivery," <i>J. Control. Rel.</i> 66: 229-241 (2000).	
		TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," <i>Proc. 5th World Congress, Chem. Eng.</i> (1996).	

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		Filing Date	July 3, 2003		
		First Named Inventor	Donald L. Wise		
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		VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," <i>J. Biomed. Mat. Res.</i> 19: 349-365 (1985).	
		WANG, et al., "Simultaneous induction of multiple antigen-specific cytotoxic T lymphocytes in nonhuman primates by immunization with a mixture of four <i>Plasmodium falciparum</i> DNA plasmids," <i>Infect. Immunity.</i> 66(9): 4193-4202 (1998).	
		WEINER, "Oral tolerance," <i>Proc. Natl. Acad. Sci. USA</i> 91: 10762-10765 (1994).	
		WOLFF, et al., "Direct gene transfer into mouse muscle in vivo," <i>Science</i> 247: 1465-1468 (1990).	
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